Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION,

Plaintiff,

v. MASTER FILE 2:12-MD-02327
MDL 2327

THIS DOCUMENT RELATES TO CASE:
WAVE 5 CASES,

Defendant. JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

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DEPOSITION OF SCOTT A. GUELCHER, PH.D.
AUGUST 17, 2017

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Deposition of SCOTT A. GUELCHER, PH.D. held at Butler Snow, LLP, 150 3rd Avenue South, Suite 1600, Nashville, Tennessee, commencing at 8:30 a.m., on the above date, before Gina Hawkins, Tennessee Licensed Court Reporter.

I N D E X

E X H I B I T S

A P P E A R A N C E S

(Appearing on behalf of the Plaintiff)

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SCOTT A. GUELCHER, PH.D.

after having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. THOMAS:

Q Good morning, Dr. Guelcher.

A Good morning.

(Exhibit 1 was marked for identification.)

BY MR. THOMAS:

Q Dr. Guelcher, I'm going to hand you Deposition Exhibit Number 1. This is a paper from the Journal of Biomaterials Science, Polymer Edition, 2017 titled "Oxidation and degradation of polypropylene transvaginal mesh."

You're familiar with that document, aren't you?

A Yes.

Q You're one of the authors on this paper?

A Yes.

Q And in fact, you're the corresponding author?

A Yes.

Q What does it mean to be a corresponding author?

A That means that I handle all the correspondence with the editor, editorial office.

Q And do you handle any questions that people might have about the content of the study for readers?

A Well, yeah, all the authors together respond to comments from reviewers, and then I send the final response to the journal.

Q Okay. You're the point person for any issues that might arise around the article?

A That's right.

(Exhibit 2 was marked for identification.)

BY MR. THOMAS:

Q Let me show you Deposition Exhibit Number 2. And Deposition Exhibit Number 2 is titled "Supplemental Data, Supplemental Materials and Methods."

Do you recognize this document?

A Yes.

Q And is this the supplemental data that's referenced on the first page of Exhibit Number 1 down at the bottom?

A Yes, I believe so.

Q And this is the data -- Exhibit Number 2 is the data that Exhibit Number 1 refers to for the tables and figures contained in that Exhibit Number 1; is that correct?

A Yeah. There's a citation to the supplemental data in the paper.

Q Was the supplemental data made available at the same time as the original study?

A What do you mean by "made available"?

Q At the time that you published Exhibit Number 1, was Exhibit Number available?

MR. JACKSON: Objection to form.

A I didn't check that, but that's usually the standard practice in the papers published. It's typically published with the supplemental data at the time.

BY MR. THOMAS:

Q That was -- I'm sorry. I didn't mean to interrupt you.

That was your intent at the time to have the Exhibit Number 1 and Exhibit No. Number 2 available to the reader at the same time?

A Yeah, but that's the editorial office. I mean, you know, I submit the documents to the editor at the same time, and then the Journal makes it available online. So I can't control that.

That's the way it's typically done, but what I control is what I submit to the editorial office.

Q Okay. Who is Anne Talley?

A She was my former graduate student.

Q And what contribution did Anne Talley make to this Exhibit Number 1?

A I believe that she -- let's see if I addressed that in the paper. I don't remember if I did or not.

Q I don't believe that you did, but take your time.

A Yeah, so Anne, I think, did the analysis of the FTIR data to calculate the peak areas. I believe she did some of that work.

It's hard to remember exactly what else. She contributed to the writing, probably some of the methods, but it's hard to say, you know, exactly who wrote what. I would say she contributed to writing and analysis of the FTIR data.

Q And what is her area of expertise?

A Well, biomaterials. She works for FDA now, so has expertise in biomaterials.

Q And who is Bridget Rogers?

A So Bridget Rogers is an associate professor in my Department of Chemical Engineering at Vanderbilt.

Q And what contribution did Ms. Rogers make to this Exhibit Number 1?

A So her area of expertise is in films, XPS. So her contribution was, she did the XPS experiments, she analyzed the data. She largely wrote a lot of the parts of the paper on XPS. That's her area of expertise.

Q And in the report I note that Dr. Iakovlev, who's also an author, contributed the AMS explant and also cleaned the AMS explant.

Did Dr. Iakovlev make any other contribution to Exhibits 1 or 2?

A He assisted with writing the manuscript.

Q I'll note that Dr. Dunn, Russell Dunn, who's also an author, his company is noted as a sponsor of the study.

What other contribution did Russell Dunn have in Exhibits 1 and 2?

MR. JACKSON: Object to form of the last question.

A So Dr. Dunn, his company, as you said, funded the study. He performed the experiments. I should be more specific.

The FTIR and the SEM measurements were performed by Dr. Dunn and people that were being supported by the grant, I believe. He would know more of the details, but I would say that he did the FTIR and SEM experiments.

BY MR. THOMAS:

Q And what contribution did you have to Exhibit Number 1?

A So I wrote the first draft of the paper. I compiled all the data from my collaborators, my student. I prepared some of the figures, I think, and I did most of the writing.

Q Who owns the FTIR equipment that was used in the study?

A I don't -- I don't know. Russell Dunn would know the details of that. I don't know who owns that equipment.

Q Same answer for the scanning electron microscope and XPS?

A No. The SEM is a Vanderbilt resource, and so is the XPS.

Q Who was the person responsible for discussing with Vanderbilt the use of the XPS and SEM equipment for purposes of Exhibit Number 1 and 2?

A Well, that would be Dr. Dunn.

Q Did you have any involvement in that?

A Any involvement in what specifically?

Q In any negotiations or discussions with Vanderbilt about the use of the XPS and SEM for the work that's reflected in Exhibits 1 and 2.

A No, I don't believe so. That was Dr. Dunn's responsibility.

Q Did you have any control over the disbursement of funds that were provided by Russell Dunn's group for this study?

MR. JACKSON: Objection to form.

A No, I didn't.

BY MR. THOMAS:

Q Do you know whether Vanderbilt was compensated for the use of their XPS and SEM equipment?

A So the SEM is a core resource at Vanderbilt. What that means is, you pay a user fee to use it. And when

it says -- so in the acknowledgments we say that this work was supported by Polymer Chemical Technologies. Polymer Chemical Technologies paid the user fee for that SEM.

I don't remember how the XPS was handled. For the SEM it's a core resource, so the University was paid through that billing agreement.

Q What do you mean by "core resource"?

A So large pieces of equipment like SEM are -- it's not possible for individual professors to own things like this because they're so expensive to maintain, but many people want to use it. So we have large equipment like SEM that isn't a core. In this case it's the Institute for Nanoscale -- Nanoscience and Engineering. And in order to recover the costs of using the equipment, that core charges an hourly rate, and then that rate has to be paid. In this case it was paid by PCT.

So it's a facility that's owned by the University, and anybody can access it by paying the user fee. It's an hourly fee.

Q And did I understand you to say you do not know how the University was compensated for use of XPS equipment?

A I do not. That would be -- so the XPS is owned by the University. Dr. Rogers is the one who coordinates the use of the XPS.

There have been some changes to how that is

managed, and I just don't remember what was in place at that time.

Q At the time that you used the University's equipment, are you required to disclose the purpose for which you're using it?

A No. It's -- you just pay the user's fee. I mean, you would have to disclose it if it's potentially -- you know, if it's a concern about safety, but this is a pretty standard analysis. So typically that's not done.

Q Did you -- did you or any of the other authors, to your knowledge, disclose to the University that you were using their XPS and SEM machines for this specific study?

A No, there would be no reason for that.

Q Okay.

A That was handled through the -- Dr. Dunn had his -- PCT had a contractual relationship with the University, and so once that relationship is established, you're free to use the resources like you would for another --

Q Doctor, what was the purpose of Exhibit Number 1? What were you trying to set out to do?

A I believe we addressed that in the abstract. So in the study we hypothesized that polypropylene oxidizes under in-vitro conditions simulating the foreign body reaction so that the purpose was to test that hypothesis

that polypropylene would oxidize under stimulated in-vivo conditions.

Q What does this study tell us about any oxidation under in-vivo conditions?

A Well, we used a test solution. I believe that's addressed on page 3, the last paragraph in the introduction. We used an oxidized media that comprised 20 percent hydrogen peroxide and the cobalt chloride, which causes this reaction to form hydroxyl radicals, which are a form of reactive oxygen species that's present in-vivo, so we were simulating that -- those oxidative conditions.

That paper has been known for some time and cited a number of times. So that was the -- that was the approach.

Q You also it tested an AMS explant; correct?

A That's right.

Q And for what purpose did you test the AMS explant?

A I hope it's okay, what I'd like to do is read -- discuss right from the paper what I said because it's been a while. I don't -- I'm just taking a little time, if that's okay.

Q Sure. Let me ask you this question: Did you review Exhibits 1 and 2 prior to your deposition?

A I did, but I didn't have a lot of time. This

just came about pretty fast, and I published this awhile ago.

So I've reviewed these documents. I just want to be careful. So I believe that you asked me what's the purpose of the -- why did we test the explanted fiber? That's what you asked?

Q That's right.

A I can't find what I'm looking for right now, but basically we were testing the hypothesis that this oxidation could also happen in-vivo. That was the question we were asking is, can fiber also be oxidized in-vivo in the body.

Q And you obtained this AMX -- sorry.

Doctor, you obtained this AMS implant from Dr. Iakovlev?

A That's right.

Q Do you know what kind of implant it was?

A We had some discussion about this. I can tell you if it's in the -- because of patient confidentiality, we were limited in what we knew, but I can tell you what we did know.

So all we know is that it was an AMS midurethral sling. We don't know the product. We just know that it was a sling.

Q Do you know how long it was in the patient?

A We do not.

Q Do you know the reasons the midurethral sling was removed?

A Well, it was explanted for complications other than mucosal erosion. This is what we know from the records.

Q Is that all that you know?

A Yeah. We put in the paper what we knew about the explant.

Q I'm sorry if I asked this already. My head is a little fuzzy, too.

Doctor, do you know how long the AMS implant was in the patient before it was removed?

A Yeah, I said unfortunately we don't. This is all we could get from the patient records is that it was explanted for some complication other than erosion.

Q Doctor -- sorry. You finished?

A Yes.

Q Doctor, the paper reports that Dr. Iakovlev cleaned this AMS explant; correct?

A That's right. He did that work.

Q Did he do that at his laboratory in Toronto?

A He did.

Q Did he record his methodology in removing the tissue, as he's explained in the report?

A So we explained -- he does a microscopic

dissection where he can remove pieces of tissue using some small tweezers under a microscope, and a scalpel blade he used as well.

So he developed this technique, and I believe he's been using it for some time.

Q Have you seen a written protocol for the cleaning of the mesh that's described in Exhibits 1 and 2?

A I don't remember. I don't know that I've seen a written protocol. I mean, the level of detail that we provided in the paper is consistent with what, you know, you typically would do in a paper.

I haven't seen -- I don't know if he has a detailed protocol. I just know that he's done this for some time.

Q Do you know whether he has any notes or records of the procedure he followed to clean the AMS explant?

A I don't know the answer to that either.

Q Do you know if he has any photographs that he took during the cleaning procedure?

A Again, I suspect that he does, but I haven't seen them. He would be able to provide that information.

Q As a part of this study, was it your practice to keep laboratory notebooks of the work that you performed?

A Again, Dr. Dunn did all of that. So, again, just to make it clear, Dr. Iakovlev prepared the fibers. Dr.

Rogers performed the XPS. Dr. Dunn did the FTIR and SEM. So they would have that experimental data. I don't have it. I didn't do the work.

Q Have you reviewed any of the experimental data, written experimental date upon which Drs. Dunn, Iakovlev, Talley and Rogers relied to generate the data that's in Exhibits 1 and 2?

A Yeah, I've reviewed the raw data with them as we were writing the paper, but I don't have it. I mean, as we were preparing the figures and writing the manuscript, I reviewed the data with them.

Q Did you have it in electronic form or hard copy?

A I don't remember. I think -- I don't remember. Usually what I do with my students is, I get the figures, and then in some cases I'll put the figures together into panels, but I don't -- we don't -- I don't necessarily keep the raw data on the studies on my computer. We store that elsewhere. I mean, I don't --

Q Where did you store the raw data that was used to generate Exhibits Number 1 and 2?

A Again, that would be Dr. Dunn's data. I didn't do it.

Q Dr. Guelcher, I'm not trying to be difficult. You testified that you reviewed the raw data generated by these folks as you did their work with them.

A Yeah.

Q At some point you had access to that data. What did you do with the data that you reviewed with your co-authors as they generated the data that goes into Exhibits 1 and 2?

MR. JACKSON: I think that's asked and answered at this point.

A I don't remember the details. This was awhile ago. But, for example, you would run an FTIR spectrum on the FTIR machine, and those data would be stored in that computer, and then we would pull them up and look at the data.

And then the final disposition of those data, I don't know if Dr. Dunn left it on that computer or moved it off and stored it somewhere else. I don't know. It's not my data.

BY MR. THOMAS:

Q Is it fair to understand that as you sit here today, you don't have access to any of the raw data underlying Exhibits Number 1 and 2?

A What do you mean by "access"?

Q Could you get it if you wanted it?

A Yeah. I would go to Dr. Dunn and get the data.

Q And you would expect Dr. Dunn to have all of the data that underlies Exhibits Number 1 and 2?

A That would be my -- I mean, when you do collaborative scientific research projects like this, each investigator controls his or her -- it's just the way -- the collegial way to do it. Each investigator controls his or her raw data, is responsible for storing that under some kind of long-term conditions, but we do so many runs on the instrument, it's not typical to leave all the data there. At some point somebody takes it off and stores it somewhere, but I don't typically do that.

Q I understand. I'm just trying to figure out where it might be.

A Well, Dr. Dunn would have it. I mean --

Q Would he have -- are you finished?

A Yeah.

Q Would Dr. Dunn, as far as you're concerned as the corresponding author, have control of the data from Talley, Rogers, Iakovlev and Dunn?

A I want to be really clear because I feel like there's some confusion. I may take a little bit of time to answer.

Q Sure.

A So just to make it clear, Dr. Dunn did the FTIR and the SEM, or people that worked for Dr. Dunn. I don't know the details of his arrangement. He's the PI for that part of the work, principal investigator for that part of

the work. For the FTIR and the SEM, he would have those raw data.

Now, my student didn't do those measurements. She did the analysis. But again, everything was given back -- Dr. Dunn would have all of that. The XPS was done by Dr. Rogers, so she would have -- any additional data on the XPS Dr. Rogers would have.

And then the only thing that Dr. Iakovlev would have would be protocols and pictures, et cetera, of how he prepared the fibers. He would have that.

So if you wanted all that, you'd have to go to them to get it because it's their work. It's not my work. I worked with them to write the paper. I concede to the hypothesis and took the lead on writing the paper, but I relied on my colleagues to provide the raw data. So that's why I don't have it.

It is -- I don't want to give the impression that it's not accessible. It's just under the control of my colleagues who prepared it.

Q But to be clear, if you wanted access to the data, you could request it of them, and they would give it to you?

A I'm not comfortable doing that because it's not my work, and it's a legal proceeding. I think it would have to go through them, not through me. That's just a collegial

way -- this was a research project. I want to make it really clear. This was not testing for litigation. This was a research project.

Q Doctor, is it fair to understand you didn't ask Dr. Dunn or any of the other co-authors for their data in order to prepare for this deposition?

A I did not because I didn't think it was appropriate.

Q All right. Let's go to Exhibit Number 1, please, and go to page 7.

By the way, in preparation for your deposition, have you read the expert reports of Dr. Thames and Dr. McLean?

A I've read them in the past several months. I didn't have time to go through them again last night, but I have read them in the past several months, I'd say.

Q Have you read their criticisms of this -- what I'll call the Talley paper?

A I have, but I don't remember exactly what those were.

Q When you read the criticisms of the Talley paper, did you go back to investigate those criticisms?

MR. JACKSON: Objection, form.

A Investigate? I don't remember. I mean, I don't know how appropriate it is to talk about other litigation

other than this but, you know, I am working on other cases, and in the context of that I read their comments, and I made some replies in some reports. But I don't -- I just -- it would help me if you had me look at something. I'm going on my memory. It's just a little tough.

Q All I can ask you to do, Doctor.

When you say you made some replies in some reports, are those expert witness replies?

A Yes. It's not public.

Q Are these the ones you submitted in Australia?

A Yeah, I believe that I did, but I just can't remember -- I have read it, and I have thought about it, and I thought that I responded to it, but I just can't remember the details.

Oh, well, maybe one thing I can remember is that -- well, you know what? I'm going from my memory, so I just want to be -- I just can't remember details right now.

Q Sure. What's your best recollection?

A I just can't -- I can't remember right now what I wrote.

Q Okay. Are you on page 7 of your report?

A Yeah.

MR. JACKSON: When you say "report," do you mean the article?

BY MR. THOMAS:

Q I need to start over because I got the wrong page. Would you go to Exhibit 1, please, and page 10.

A Oh, okay.

Q Page 10 has a Figure 4 that has four categories of images marked A through E. What's the purpose of Figure 4?

A Would you like me to talk through the message in Figure 4? Is that what you're asking me?

Q That's right.

A So in Panel A -- and again, this is Dr. Rogers' experiments. But in Panel A, these are SEM images of the explanted fibers from the AMS mesh, and she focused on what's called an area of interest, which is that white box. And that area of interest is exposed to X-rays, and then in response you get photoelectrons that you can basically use to determine the composition of what -- of that surface in that small box.

Q What does it mean for untreated and scraped?

A That's defined in the paper. Let me give you a precise definition.

So the untreated, basically -- it wasn't scraped. We just -- Dr. Iakovlev literally -- my understanding was, he explanted the fibers from the mesh under the microscope, and he didn't do the dissection. And then the scrape -- he

did the microscopic dissection. So that would be the difference between the two groups.

Q Okay.

A So what's shown in Panel D, those are the -- those are the peaks that come off, and there's a mathematical analysis that Dr. Rogers did for those peaks to actually come up with what's shown in Panels B, C and E. Sorry, did you --

Q Just to make it clear, Panel D is the XPS testing?

A Yeah. So Panel D is the emission spectra. So in Panel D you're looking at the energy of those photoelectrons that come off the surface, and so you get these distributions. And then those raw data are analyzed to prepare the plots in Panels B, C and E.

Q What is the data that's represented in Panel B?

A So the emissions spectra tell us something about both the specific atoms that are on the surface as well as the binding states. So in Panel B, this is, we show, carbon, oxygen and nitrogen. And the point in Panel B is that the untreated fibers had nitrogen and oxygen, as you would expect, because these weren't treated, right, so there were -- again, the purpose of the scraping that Dr. Iakovlev did was to remove the protein, right, and so you would see oxygen and nitrogen on the surface, but after scraping we

don't see any nitrogen. So that would suggest there's no protein.

Q What's the atomic percentage figure on the -- I guess that's the -- on that axis?

A Well, that's the percentage of each atom that's in the spectra. So it's 80 percent carbon, 15 percent -- it's the percentage of each atom.

Q Do you expect, do all these add up to 100 percent?

MR. JACKSON: Objection, form.

A I think so, but the raw data are in the supplement.

BY MR. THOMAS:

Q I'll get to that in just a minute.

A You know, lit's the percentage of the total of everything that comes off the surface.

Q Okay. What is Panel C?

A So in Panel C we calculated the ratios of each of those atoms. So its oxygen to carbon -- so Panel C is basically calculated from Panel B. That would be oxygen to carbon, nitrogen to carbon and nitrogen to oxygen ratios.

Q Why do you do that?

A Well, the purpose here was to see, again, the nitrogen to carbon and nitrogen to oxygen ratios go way down after scraping, which basically the same point here is to

show that your scraping is removing the proteins, but there's still oxygen on the surface. So the only explanation for that would be oxidation. That's the message.

Q Just to nail this down, is there any purpose other than to show the effect of the scraping for Panels B and C?

A Well, it's not quite that black and white. I mean, I think -- the purpose of doing the scrape and the untreated is to show that, you know, before cleaning there's protein on the surface, and then after cleaning the protein is almost completely removed. There's very little nitrogen. In a lot of samples we didn't see any nitrogen, but there's still oxygen. And so the question then is, where does that oxygen come from? And what we believe is, it's coming from oxidation because there's no nitrogen on the surface, which would imply there's no protein.

So that's why we did both was to look at the change, you know, to try to be rigorous about it. That's why we did both.

Q What's the purpose of Panel E?

A So Panel E shows the bonding configurations.

Q What is a bonding configuration?

A So if we look at mechanism of degradation of polypropylene. You would expect carbonyl groups, which is

the C over on the left. That's the carbonyl.

And then the other binding configuration is what Dr. Rogers would call carboxylate, and this is similar to the hydroperoxide degradation product.

So the point here is to show that before and after scraping we see both of those. Again -- and this is a point that, you know, Dr. Thames has made in his work about the protein. Proteins have carbonyl and carboxylate bonds. So if you have protein on the surface, you would expect to see quite a bit of bonding, which we do. But even after that protein has been removed manually, and then you don't see any nitrogen, you still see these carboxylate and carbonyl groups. That's the purpose. So it's further supporting what we saw in Panels B and C. We see the types of bonds that you would see for oxidized polypropylene even after the protein has been removed.

Q What's the significance of the carbonyl numbers standing alone?

MR. JACKSON: Objection, form.

BY MR. THOMAS:

Q Or do you have to look at them side by side in order to make --

A Oh, no -- well, how do I answer that? I'm going to try to answer your question. If you don't like it, try again. I won't be offended. I'm trying to deal with this

in a rigorously scientific way.

Q Maybe I can help you a little bit.

MR. JACKSON: He was going to answer the question.

BY MR. THOMAS:

Q Fine. I'm just trying to make it easier on him. Go ahead.

A The reason we did both groups is because I think it's scientifically more rigorous to took at the change.

So you could just -- you could just clean the fiber and see carbonyl and carboxylate on the surface and conclude that it oxidized, but I think it's more rigorous to look at the untreated fiber as well, where you would expect to see a lot of carbonyl and a lot of carboxylate, which we do. Okay, there's protein on the surface. When I remove what I believe to be protein, those bonds come down, which I would expect, but they're still there.

So I think it's -- I prefer to really talk about it like it is in the paper, discussing it in its totality. And the reason we did those controls was to really give a good rigorous analysis and scientific perspective on what we did.

So I would say if I look at -- I know it's a long answer. But the fact that I see carbonyl on a scraped fiber would tell me -- this shows no nitrogen -- I would conclude

that it's oxidized. I think having the untreated groups strengthens the rigor of that conclusion. That's the way I would answer your question.

So I do think it stands alone, but I like the way I present it in the paper where we do both.

Q What is the takeaway from Panel E?

A Panel E. Well, the takeaway would be that after you remove the protein, you still see carbonyl and carboxylate bonds that are consistent with the degradation products of oxidized polypropylene.

Q Let's go to page 4 of Exhibit 2. Keep that page open. You're going to need it.

A Okay. Page 4, okay.

Q Do you have that in front of you?

A Yes.

Q Do you see Table S6?

A Yes.

Q Table S6, page 4, Exhibit 2, is titled "Summary of relative amounts (percentage) of the various C 1S bonding configurations present on scraped fibers."

A That's right.

Q And that is the basis for the scraped fibers figure in Figure E on page 10 of Exhibit 1; correct?

A That's correct.

Q And S6 is where Ms. Rogers has recorded the data

that she collected from her XPS; correct?

A Yes.

Q And if you looked at Table 6 on page 4 of Exhibit Number 2 where it says, 288 eV, that's the XPS column for carbonyl group; correct?

A Yes.

Q And of the five measurements she took, three were nondetect; correct?

A That's right.

Q And then she recorded measurements for fibers 23 and 24. At the bottom is a column for mean plus or minus SD. What does that mean?

A That's the mean plus or minus the standard deviation of those five numbers.

Q What's the purpose for including that column in this kind of table?

A You mean the row?

Q Yes, the row. I'm sorry.

A Well, we calculate the average in the standard deviation so we can compare the different groups. We can quantitatively compare the groups.

Q From an analytical perspective, what's the meaning of the mean plus or minus the standard deviation for the carbonyl group, which is .4 plus or minus .6?

A Well, that would be the standard deviation of the

measurement. It's to measure the spread of the distribution of the data.

Q And so .4 is the mean --

A Yes.

Q -- of the values; correct?

A That's right.

Q And .6 is the standard deviation or the error rate; correct?

A I don't know if I'd call it error. It's the distribution of the samples.

So we have -- like you pointed out, there were three of them that basically were zero. We couldn't see anything. It's probably not zero, but practically speaking, it's zero. We couldn't measure it. So for two of them we measured it. We averaged them together to give -- that's what we did.

So there's a distribution of measurements. That's what's reflected by the standard deviation.

Q What does it mean when the measurement is .4 plus or minus .6? What does it mean to you as a chemist looking at this data?

A It's the spread of the distribution.

Q Does it tell anything to you about the validity of the data?

A What do you mean "the validity of the data"?

Q The accuracy of the data as reported.

MR. JACKSON: Objection, form.

A I mean, the data that are reported. There are five measurements for the amount of carbonyl on each of the fibers. That's what reported. This is a statistical calculation.

The data are reported as they are, and some -- I'm going to say zero, even though, just to make it easier. It's not zero. It's some number that was so small we couldn't measure it, but we'll call it zero.

Three of them we didn't see the carboxylate, and two of them we did. So what that tells me is that those regions, those very small regions that were probed, after removing the protein, what we thought was the protein, it could have removed some of the oxidized polypropylene. Maybe that particular region didn't see much oxidation. We don't know, but we couldn't measure oxidation. We didn't see it. When I say we couldn't measure it, we didn't measure the presence of the carbonyl on those three regions. That's what it means.

BY MR. THOMAS:

Q Doctor, in statistical analysis, in order to have reportable data, don't you want the mean to be greater than the standard deviation?

A I mean, standard deviation, it's a measure of the

spread of the distribution.

I explain in the paper how we did that. I mean, it's just a measure of the spread of the distribution. I'm not really sure what you're asking.

Q Can you answer the question?

A I'm trying to, but I'm not really sure what you're asking me.

Q In reporting compiled data like you have here, when you subject it to the mean versus the standard deviation, don't you want to have the mean to be greater than the standard deviation in order to have reportable data?

MR. JACKSON: Objection, form.

A But that doesn't -- no, I don't agree with what you're saying. I mean, that's a calculation of the data to enable comparisons between groups. The data stands as it is, you know. I said there's three of them we did not detect carboxylate. Two of them we did. From that distribution, we can calculate mean and the standard deviation, but we -- it doesn't detract from the data. The data are the data. They're distributed as they are.

This is just a means for modeling the data or explaining it. It doesn't detract from the data.

Q Why didn't you report, in Exhibit Number 1, the fact that the mean was less than the standard deviation?

A I mean, I wouldn't normally report that. I mean, we did the -- we tested -- we compared the groups using different tests, and we plotted it. We showed the standard deviation. It's just a means of characterizing the distribution.

I mean, if you have a distribution centered at zero, then the means is going to be zero, and the distribution is going to be -- it's an analysis technique. It's not -- you can't control how the data distributed, how it is distributed.

Q But the meaning of the data is impacted by the mean compared to the standard deviation; correct?

A Well, the statistical testing is -- no, no. When I did the -- I'd have to go back and look at exactly what I did.

We compared distributions. This is just written here as a means for the reader to, you know, get some kind of understanding of how the data are distributed, but it doesn't impact it. The data are the data.

Q Next column on Table S6, again, which was used for Table E in Exhibit 1; correct?

A You know, Figure 4E, that's what you mean, right?

Q Correct.

A Yeah, okay.

Q It says, "287 eV, RC COOH." What does that

represent?

A Well, it's just the nature of that carboxylate bond.

My understanding -- again, this is Dr. Rogers' work. But, you know, my understanding is, you can basically see that it's -- 287 electron volts is consistent with carboxylate type of bonding where you have a COOH -- and it doesn't tell you the actual details of the bond, but you know that you have that kind of configuration where you have carbon bonded to oxygen bonded to oxygen bonded to hydrogen. There could be several different types of bonding configurations, but it has this general structure.

So it's just too difficult to, you know, say exactly what the bonding configuration is, but it's some form of this.

Q Okay. Now, Doctor, if you look at S6 under the carboxylate bond column, they record values for fibers 5 and 8; correct?

A 5 and 8, yeah. 2.5 and 2.3, is that what you mean?

Q That's correct. If you go to page 2 of Exhibit 2 --

A Yeah.

Q Go to page 2 of Exhibit 2.

A Okay.

Q Do you have that?
A Yeah.
Q And page 2 of Exhibit 2 shows the XPS images on which the author relied to generate the figures that are contained in Table S6; correct?
A Yes.
Q And under scraped fiber, Figure S2, there are images for Figures 5 and 8; correct?
A Yes.
Q And on S6 on page 4 for fiber 5, it shows a carboxylate bond value of 2.5. Do you see that?
A Yeah.
Q If you look at fiber 5 on page 2, there is no carboxylate peak of 2.5. Do you agree with that?
A I don't know. She didn't label it. She prepared -- Dr. Rogers prepared these figures. I don't know that I would say it's not there. Just, it's not labeled.
Q Do you see anything that resembles a carboxylate peak of 2.5 on Figure 5?
A I can't tell by looking at this resolution. I'm having a hard time seeing it.
Q You can't see it?
A Yeah, again, it's not my data. You know, Dr. Rogers did this analysis. There's an analysis that's done of these data that you have to deconvolute the peaks, and

Dr. Rogers did that work. She would be the one to answer details about that.

It's not -- I agree that it's not labeled in the diagram.

Q And you can't see a peak that resembles 2.5 in a carboxylate area, can you?

MR. JACKSON: Objection, asked and answered.

A Yeah, I mean, I think I answered it. You know, it's very small. I'd have to look at her analysis of how she did that.

BY MR. THOMAS:

Q Okay. The same question for fiber 8 in Table S6. It shows a carboxylate peak of 2.3?

A Yes.

Q If you look at fiber 8 in Figure S2 on page 2 of Exhibit 2, there's no carboxylate peak of 2.3 appearing in that image as well?

A Same answer for number 5. I mean, again, she didn't label it. I'd have to look at her analysis to figure out what she did there.

Q Did you -- did you prepare Figure E -- Figure 4E on page 10 of Exhibit 1?

A I think so. I know I prepared Figure 4. I don't know. I can't remember if I did it or if Anne did it.

Q Would you agree with me that Figure 4E includes

the values 2.5 for fiber 5 and 2.3 for fiber 8 in the bar chart for the carboxylates?

MR. JACKSON: Objection to form.

A Those are the numbers that are plotted in the panel.

BY MR. THOMAS:

Q Okay. And do you know the statistical impact of removing those values from what you show in 4E?

MR. JACKSON: Objection to form.

A I haven't looked at that. I relied on Dr. Rogers for this analysis, so I'd have to go back to her and discuss this with her. We calculated -- Anne and I did this together. I can't remember who did what. We were relying on the numbers that she provided in the table.

BY MR. THOMAS:

Q And the table you're referring to, Table S6?

A S6, yeah. We didn't go back and -- this is her -- this is what she did. She did the analysis of the XPS. So we were relying on her analysis, so I'd have to go back to her and discuss that with her.

Q Since you wrote this paper, you've become aware that both Dr. Thames and Dr. McLean have raised this criticism of this paper, haven't you?

MR. JACKSON: Objection to form.

A I haven't heard -- I don't remember seeing this

point. They wrote some other things about it. They -- I mean, they wrote other things. I've never seen this, though.

BY MR. THOMAS:

Q Since the publication --

A Just to clarify, this is the first time I've been aware of this viewpoint.

Q Since publication of the Talley paper, have you had discussions with -- is it Dr. Rogers?

A Yes.

Q -- with Dr. Rogers about the data in Table 6 as compared to the XPS on page 2 of Exhibit 2?

A I haven't discussed this with her for a while, probably since we wrote the paper.

Q Okay. Staying on page 4 of Exhibit 2, who prepared the tables in S4, S5 and S6?

A Dr. Rogers produced these. I mean, I may have -- I can't remember who did -- I may have made the table based on the numbers that she gave us, but she produced those numbers.

Q Okay. Who designed the tables, for lack of a better word? Who came up with the format for the tables?

A Dr. Rogers.

Q Do you see the column on S4 of 284.8 eV?

A Mm-hmm.

Q It's labeled "CH." What does CH mean?

A Well, that would be the percent of carbon in that carbon hydrogen bonding configuration. So that would be like a hydrocarbon bond. CH is what percentage of the carbon is bound to the hydrogen. The carbon bond is what percentage of your hydrogen bonds, is my understanding.

Q And you mentioned before the concept of deconvolution. What is that?

A Well, my understanding is, you have these overlapping peaks, you know, and these are distributions of energy. So they overlap in their mathematical methods that you can use to determine, you know, which peak corresponds to which type of bond or atom. That's the type of work that -- that's what Dr. Rogers does.

Q Do you consider yourself an expert in the area of deconvolution?

MR. JACKSON: Objection to form.

A Well, this is -- this is a method that -- I mean, I think I've used it before where you have it any kind of overlapping peaks and any kind of analysis. We can see this in GPC or HPLC or different chromatography. You can have these overlapping peaks. So you have to find a way to calculate which is which because the peaks -- I'm not explaining it very well.

You have to be able to separate that region of

overlap. Like I said, there are methods that have been -- that are used for this. I don't remember the details of those right now, but it's a pretty standard approach.

BY MR. THOMAS:

Q Okay.

A Again, with XPS, this is again Dr. Rogers' work. And I've published other papers with her on XPS, and she did the separation of the peaks.

Q In Tables 4, 5 and 6, the last column is 284.3 eV, and there's no description of what that area is. Do you know what that is?

A So my understanding, that particular peak is often what people refer to as adventitious carbon. I think it's in the paper. Let me see if I can find it here.

Q I'm not familiar with that term. What did you call it, adventitious?

A I think the technical term is "adventitious." Let me see if it's discuss in here, and then I can give you a more precise answer. Maybe we didn't discuss it.

Q I don't remember seeing it.

A Basically, I think the best way I can answer that is, it's some form of carbon bond that we can't attribute. It's difficult to say exactly which bonding configuration it could be. So it's a carbon bond, but we don't -- like with these other bonds we can say it's carbonyl or carboxylate,

but we can't say specifically which type of carbon bond probably because of overlapping peaks. That's my understanding.

So I would say that it's a carbon bond, but we can't provide the details, so we listed it just because -- the numbers need to add up. We listed everything that we saw. It's some form of carbon bond that we don't know the details about. I would probably say it that way.

Q Would you defer to Dr. Rogers for an answer on that?

A Yeah, she could give a more -- Dr. Rogers could give a more maybe detailed answer on that. I mean, I think she would say the same thing. We just don't -- it's a limitation of the method. You can't -- you see a peak there, but ascribing that to a specific bonding configuration is challenging, so we just report the number at the peak.

That's why we report it. Like you can see in the table, we don't list a bonding configuration because we don't know.

Q If you look at page 1 of Exhibit 2, at page 1 of Exhibit 2 right in the middle of the page it says, "The energy scales at the high-resolution spectra were calibrated to place CH2 bonding in the carbon 1s spectrum at 284.8 eV." Do you see that?

A Yeah.

Q And we go back now to page 4 of the same exhibit, you see 284.8 eV. It says, "CH" as opposed to "CH2." Are those the same?

A I think so. I think the CH2 bonding, I think what that's referring to is a methyl group, which would be a carbon bonded to two other carbons bonded to hydrogens. So I think these are the -- I think what she's saying here is that basically the scale was calibrated so that those methyl carbons are showing up here at 284.8. I think it's consistent. That's my understanding.

Q Has anybody ever told you the column that's marked "CH" should be "CH2," and the column that's left blank should be "CH"?

A I've not heard that before. Yeah, I'm not --

Q Do you know why that wouldn't be true?

MR. JACKSON: Objection to form.

BY MR. THOMAS:

Q Does that sound implausible or impossible to you, as a person involved in this study or as a person with knowledge of this test?

MR. JACKSON: Objection to form.

A Well, I think as I answered you before, it's not consistent with my understanding of the test.

My understanding is that this is a carbon

hydrogen bond and this is some form of carbon bonding configuration that we can't -- I mean, if we could ascribe this to a specific bonding configuration, we would have done that. That's my understanding. I'm going to look at it more. I hadn't heard that before.

Q So just to be clear, the first one you mentioned is the CH, 284.8. The second one you described was the last one, which was 284.3, which is the one not labeled in the exhibit; correct?

A Yeah, and I think we didn't label it because, again, we can't say with certainty what that bonding configuration is. It's an observation that we needed to report, but we did not assign a bonding configuration because we weren't confident in that. It's part of the total signal that came of the fiber, so we reported it.

Q Okay. So in Figures 4 and 5, if you note, that you have four nondetects in the last unlabeled column and then values of 21.9 and 23.5.

Do you have any explanation for a nondetect in 4 and a value of over 20 percent for the fiber 17?

A I'm confused about where you're talking about. That table? I don't, other than what I gave you, that it's, you know, it's a form a carbon bonding that's -- I would say that we don't believe it's carbon and oxygen bonding like the first two columns, but it's some form of carbon bonding

that we can't say what the exact nature of the bond is.

Q If you look at Table S4, fiber 9.

A Yeah.

Q If you go across, those columns should add up to about 100; right?

MR. JACKSON: Objection to form.

A I think they should, yeah.

BY MR. THOMAS:

Q If you add them up, they add up to 104.8. Do you have any explanation for that?

A No. I'd have to look at that.

Q Would you defer to Dr. Rogers for her explanation of that, or could you answer that question?

A I would have to talk to her to find out whether, you know, that was in what she gave me or whether, when I typed the table out in the supplement. I don't know. I'd have to check. I'd have to go back and talk to her. I couldn't answer that right now.

Q Let's go back to page 2 of Exhibit 2. Page 2 of Exhibit 2 are the XPS -- do you call them spectra or images? What do you call them?

A Spectra.

Q -- spectra that Dr. Rogers took. You mentioned the concept of deconvolution.

Do you see any deconvolution in any of the images

that are on page 2 of Exhibit 2?

A Let me be more specific about my answer. I thought this was addressed. I can't seem to find what I'm looking for.

These are -- my understanding, these are the raw data, so these are just showing the peaks. I don't think we're showing here the analysis to get those peak areas. I mean, these are just the peak -- these are the raw data, I think. She's not showing that here.

Q You mentioned that she did deconvolution of the samples she tested; correct?

A I need to find this because I'm relying on my memory. Wait a minute. Maybe it's in here. Okay. I think I found it. I'm going to be more specific in my answer. I don't want to necessarily use this term "deconvolution."

Basically, what we say in the paper is that the curve fitting to extract the contributions of different carbon bonding configurations present in the analysis area. So she did that curve fitting. I don't believe that's shown on these spectra, but she did that analysis to come up with the numbers on the table.

Q Okay.

A That's what she did.

Q And the analysis that she used to come up with the figures in the table are not available to us today; is

that correct?

A I don't -- I don't know that -- she has that. I don't have that. Dr. Rogers would have that.

Q And it's not in Exhibit 2?

A No. That sort of work is beyond the scope of what people would typically publish.

Q So is it your best recollection that Dr. Rogers did or did not do deconvolution?

A Well, like I said, I don't think I want to use that term. I want to use the term that's in the paper. I'll just be more precise that she did her fitting and mathematical analysis to resolve these, in some cases, overlapping peaks, and she did her fitting to come up with the numbers in the table. That's what she did. Exactly how she did that, I don't know.

Q How is curve fitting different from deconvolution?

A I don't -- it's the same idea. I mean, I was using those words interchangeably. I should be really precise in that she analyzed the spectra to come up with the numbers in the table. She produced -- for the paper we showed the spectra, and we listed the results of what she called curve-fitting analysis in the paper to come up with the numbers.

The details of how she did that, we probably

discussed this at some point, but I don't remember the details of how she did it.

Q As you sit here today, do you know any difference that you can explain to me between curve fitting and deconvolution?

A I was -- I was using those terms interchangeably. The point I was trying to make is that there are overlapping peaks in the spectra, and you have to use various mathematical methods to resolve those overlapping peaks, and that's what Dr. Rogers did. At some point I've been referring to that as "deconvolution." At other times I've been referring to it as "curve fitting." Basically what I'm saying is that there are overlapping peaks, and Dr. Rogers did the analysis to address that and come up with the numbers in the table. That's what she did.

Q And for questions about the analysis that Dr. Rogers undertook to come up with the numbers in the table, you would defer to Dr. Rogers?

A I would refer to her. I've done this in other -- I mean, I just published another paper this year doing very similar things, using XPS to look at a surface. I did the same thing with her there. She typically does the XPS. She does the XPS experiments herself. She does the data analysis. We talk about it, she explains the limitations. She explains what she did, and then we publish it, but I

don't remember the details of exactly how she processed those data.

Q So to answer my question concisely, if you can, you defer to Dr. Rogers for the analysis that she used, whether it be curve fitting or deconvolution, to come up with the data in the tables?

MR. JACKSON: Objection to form.

A How do I say this? Yeah, she made those decisions. She made the decision about, here's the spectra. You can look at the spectra, and you can see there are overlapping peaks. And then the XPS field, there are various accepted methods. There are, again, mathematical approaches where you could address that issue of overlapping peaks and come up with -- I mean, she makes some comments like that she's using methods that are standard and published and known, but she did it, and I don't remember the details of what she did.

Q Okay. On page 2 of Exhibit 2 --

A Okay.

Q -- the document says, "A survey spectrum was collected from each fiber analyzed. Carbon, oxygen, nitrogen and silicon were present on all samples."

Why would silicon be present on any of these samples?

A Not knowing the manufacturing history -- we

suspected it's something from the manufacturing process, but without knowing all of those details, it's hard to say for certain, but I would say probably typically, if you find something like that on the fiber, that it's going to be something related to the manufacturing of the fiber. That's our best guess.

Q Do you know the chemical composition of the Boston Scientific meshes you analyzed?

A The chemical, you mean -- the polypropylene, you mean like the formulation?

Q That's right.

A I can't remember it. I don't know. If it's a Boston Scientific product, I don't know how much detail I can give, but it's --

Q All I want to know is, does the Boston Scientific formulation of the polypropylene mesh that you analyzed contain silicon?

A Oh, I see what you're getting at. I don't know. We didn't -- that's not in the paper. I don't know.

Q And you know that the TVT formulation does not contain silicon?

MR. JACKSON: Objection to form.

A I'm trying to remember. I don't remember the formulation off the top of my head, but I can't really say.

BY MR. THOMAS:

Q Let me ask you to assume. We've done this before. Let me ask you to assume that the TVT formulation of polypropylene and its proline does not contain silicon. What could be the source of the silicon that appeared in your XPS spectra?

MR. JACKSON: Objection, asked and answered.

A Well, these are AMS fibers, so it's hard to say. I mean, I don't know. I mean, these are AMS fibers. I don't know what the formulation of AMS fiber is. We didn't look at it.

BY MR. THOMAS:

Q Okay. Fiber number 5 that had been scraped contained a small amount of chlorine. Any explanation for why chlorine might be present on fiber number 5?

A I would say it's probably similar to the silica case. We don't typically -- that would come from something in the manufacturing processing, but we don't know the source of the chlorine.

Q Okay.

A Do you want to take a break for a few minutes?

Q Sure, whenever you're ready. Let's do that.

(Recess was taken from 9:45 to 9:51.)

BY MR. THOMAS:

Q Dr. Guelcher, was there any consideration given

to conducting an FTIR analysis of the AMS explanted mesh?

A Yes, we discussed it. I can't remember if it's explained in the paper.

The problem was, as these fibers were very small, and so we were pretty constrained to -- the advantage of the XPS is, you can examine those very small regions of the fiber. I think we were really just limited on sample size to do the FTIR. We just didn't have much sample. That's what I remember.

Q Okay. Would FTIR have been your first choice?

A No, I don't think so, because, you know -- I think this is in my report. Again, with the FTIR, it's -- it has been -- you know, Clave brings it up in his paper. I've talked about it in when I wrote about Dr. Thames' study. FTIR, it's harder to be more conclusive about oxygen and nitrogen.

As I explain in the report, the EDS and the XPS are more -- they can tell you about these specific atomic concentrations. By testing fibers that have been scraped and unscraped, you know, I think XPS is a more specific technique. That's why we chose that because we can actually look at the amount of nitrogen and the amount of oxygen on the surface of the fibers.

Q Would FTIR of the scraped, explanted AMS mesh tell you the extent of your success in cleaning the mesh?

MR. JACKSON: Objection to form.

A Can I go to my report on that? I don't know if that has been entered into evidence, has it?

Can you ask that again?

MR. THOMAS: Can you read that back? I'm not sure I can remember it that well.

(Last question was read back.)

MR. JACKSON: Counsel, he said he'd like to look at a copy of his report to possibly answer that question. Is that something you could provide him?

BY MR. THOMAS:

Q I sure can, if you think that would help him. I'm trying to save time.

A I think it would. As I said, this deposition came very quickly.

Q For me, too.

A I reviewed the documents, but it helps to have things in front of me so I can, you know --

Q Doctor, I can assure you, we're both under time constraints, and I assure you I'm trying to be as efficient as I can.

A No, I understand.

(Exhibit 3 was marked for identification.)

BY MR. THOMAS:

Q I marked as Exhibit No. 3 your copy of the Wave 5

report, not the exhibits, just the text of the report.

A So the question is, would FTIR be a method for -- it's hard -- I'm going to answer to the best I can.

Q Sure.

A So with FTIR I would -- if I did -- maybe I can try answering this way.

If I did FTIR on these scraped fibers, I would probably -- I think I would expect to see carboxylate and hydroxyl bonds, as we did in the XPS. I would think I would see those in the FTIR as well.

But again, the challenge with the FTIR is that there are peaks in the proteins, and there are peaks in the oxidized polypropylene that overlap, so it's more difficult to say whether it's, you know, specifically from the protein or the oxidized polypropylene.

What the XPS again tells you is the atoms. There's so much nitrogen, so much oxygen. That's why we chose -- I think FTIR would tell you something, and of course we did FTIR in vitro. It's not that we didn't want to do it. It's just that we didn't have enough sample.

Q You relied on your visual observation of the scraped AMS explant to satisfy yourself that it had been cleaned?

A I don't think that's -- no, I wouldn't say that. I think I answered that earlier. I mean, that's why we

did -- just going back to the paper. That's why we did -- I mean, that's why I preferred this more rigorous approach of looking at the uncleaned fiber and the scraped in considering the differences because -- Dr. Iakovlev cleaned it as effectively as he could, but by doing the XPS and looking at the atoms and the bonding, you can be much more rigorous about it.

When the nitrogen goes away, I think that's a reasonable indication that the protein was removed. That's -- so I wouldn't say we relied on visual observations. We tested both. That's sort of the basis for the conclusions in the paper.

Q So had you had more sample, would it have been your preference to do both FTIR and XPS?

A We would have liked to have done FTIR. I mean, I think in these studies, the more methods you can do, you know, reviewers like to see that.

Like I said, FTIR does give you some information, but I think you need other methods in addition to that. That's what we attempted to do here.

Q Okay.

A To clarify, in-vitro we don't have the complication of the protein. FTIR in vitro is a different situation. But for explants, as I said in my report, I think there are methods that are more specific than FTIR.

Q Let's go to Exhibit No. 1, please, and go to page 7.

A Okay.

Q Page 7 in Figure 2 contains FTIR spectroscopy of three different meshes over a five-week period; correct?

A That's right.

Q And is this testing that people -- Dr. Dunn and people under his supervision prepared?

A Yeah. Dr. Dunn -- to my knowledge, Dr. Dunn ran these FTIR spectra.

Q Okay. And who prepared the text for Figure 2?

A You mean the caption?

Q Yeah, bottom of the page on page 7.

A I would say we wrote that together, probably. I mean, it's, you know -- I don't remember who exactly wrote it.

Q Do you see down at the bottom it says, "The carbonyl peak is indicated with the black arrow." Do you see that?

A Oh, yeah.

Q It's a mistake, isn't it?

A The black arrow, yeah. The carbonyl is the gray arrow. It's switched in the caption.

Q The hydroxyl peak, which is indicated as the gray area, is actually the black arrow?

A Yeah. Those are switched.
Q Okay. And we decided the XPS and the SEM are owned by the University?
A Yeah. Yeah, those are University resources.
Q Who owns the FTIR equipment?
A I'm not sure about that. You'd have to ask Dr. Dunn.
Q Do you know what kind of FTIR equipment he used?
A I don't know that we go into that in much detail in the paper, but...
Q Did you review any protocols for the FTIR testing of the three meshes that are seen in Figure 2 in Exhibit 1?
A The actual testing the acquisition of the data?
Q Right.
A I mean, we talked about it. Dr. Dunn has been doing FTIR for a very long time, so he was using methods that he's used in the past.
We didn't necessarily talk about the detailed protocol that he used. We talked about the general ideas, you know, how he would do the experiment. I mean, I just -- he has a lot of expertise in that area, so I just relied on him to do it. I knew what he was doing, but details of how he put the fibers on the instrument, he did all of that.
Q So these are three different meshes; correct?
A What are three different meshes?

Q TVT, ADV and Lynx.
A Oh, yeah. Yeah, those are the three materials that we tested.
Q And these are three materials that you placed in what I'll describe as an oxidated medium?
A That's right.
Q And then you took FTIRs before the test began?
A Yes.
Q And at week 1, week 3, week 4 and week 5; correct?
A Yeah, that's right.
Q And do you know how many -- strike that.
Are you familiar with the term "scaling" as used in FTIR?
A Scaling, that could mean -- what exactly do you mean by that?
Q Do you have any understanding what it might mean in the FTIR?
A It's kind of a broad -- kind of a broad general word. I don't -- I'm not sure what exactly you're referring to.
Q That's fine. Do you know who conducted the tests, the FTIR tests?
A Dr. Dunn, I believe.
Q You mentioned before that it might have been

someone under his direction. Do you know anybody else under his direction that might have conducted the test?

A I don't know. It's been some time. I don't know. He would have to answer that. He may have done the FTIR spectra himself. He was pretty -- I don't know the details of how he actually did it.

Q Do you know how many scans he ran each week?

A Other than what's reported in the paper, I don't remember those kind of details. Let me see what I wrote.

We didn't report the number of scans, but again, he would have that. I just don't remember how many we did.

Q Do you know the number of scans that are generally regarded as appropriate for reporting FTIR data?

MR. JACKSON: Objection to form.

A Not off the top of my head.

BY MR. THOMAS:

Q Do you know why you run multiple scans?

A Well, I mean, I would run multiple scans to -- you know, that helps you address sort of the error in measurement. So I would run multiple scans. I just don't know how many he did here. These are details Dr. Dunn would have to address.

Q How many scans would you believe you, Dr. Guelcher, believe were appropriate to address the error in your measurement?

MR. JACKSON: Objection to form.

A I just don't know off the top of my head. I can't remember.

BY MR. THOMAS:

Q And what errors can occur in measurement that you would need to address with multiple scans?

MR. JACKSON: Objection to form.

A I don't know. Just generally speaking, it's just good practice just in case there's some artifact in the measurement. You run things multiple times. I can't recall right now.

BY MR. THOMAS:

Q Dr. Guelcher, I want to direct your attention to Figure 2, the TVT, which is the top FTIR spectra that's listed there.

A Okay.

Q Do you see in week 1 that about halfway across the scan there's a dip in the spectra? Do you see that?

A Oh, yeah.

Q And that is a change from week 1. Do you see that?

MR. JACKSON: Objection, form.

A Yeah, but I believe you can see peaks like this with carbon dioxide. So you basically -- that's not -- we can see peaks like that in the spectra -- again, I'm going

off my memory here -- but it's not related to any of the actual bonds that we're looking at in the spectra.

BY MR. THOMAS:

Q I understand. Do you have an explanation for what happened between week -- from the baseline, week zero, and the first week to result in that change in that peak in the middle of the week 1 spectra?

MR. JACKSON: Objection to form.

A I can't really address that without looking at the raw data. Again, this is a published paper. These are published data. I said that Dr. Dunn collected all these data. I mean, it's kind of hard to go through -- we've seen these types of things before.

BY MR. THOMAS:

Q Do you know what it is?

A I think it's carbon dioxide, but I can't remember off the top of my head.

Q Would you defer to Dr. Dunn?

A Yeah. I know I've seen this before in some of my papers where we're looking at isocyanates. Basically, sometimes these types of things will happen in the FTIR spectra. I can say I don't think this is associated with a change in the sample. I think this came up in another deposition, to be honest with you. I'm trying to remember what I said then, but I don't think it's an actual change in

the material.

Q Is it a change in the testing environment?

MR. JACKSON: Objection to form.

A What do you mean by the environment? Maybe like the gas --

BY MR. THOMAS:

Q Something about the testing environment that altered the FTIR spectra.

A I just can't remember off the top of my head.

Q That's fine. Week 3, it looks like that peak that we just mentioned in week 1 is gone. Do you see that?

A Yeah.

Q And then in week 4 it appears again, but it's going a different direction.

A Yeah, but I don't think this is -- this is -- I think you see this in FTIR spectra, and I can't remember the details exactly of why it's there, you know. Reviewers didn't have a hard time with this. It's not relevant to the findings of the carbonyl, and it's in a totally different part of the spectra. I mean, it's -- I just don't think it's significant. It's not a significant finding. It doesn't significantly impact the finding from the FTIR data.

Q Okay. Doctor, as you look at the TVT mesh, going from weeks 1, 2, 3, 4, week 4 in the areas that you're looking at, that is, the carbonyl and hydroxyl, week 4 show

no peaks. Do you agree with that?

A You know, they're not -- if there's a peak there, it's not as big as it is in week 5. Week 5 is where we saw the peak showing up.

Q Okay. And you'll agree that the week 4 spectra is actually smoother than the spectra from weeks 1 and 3?

MR. JACKSON: Objection to form.

A I mean, there's less noise in the --

BY MR. THOMAS:

Q Yes.

A It might appear that way.

Q Do you have any explanation for that?

A Again, these are Dr. Dunn's raw data. I can't really -- I mean, again, this is peer-reviewed. People looked at this and didn't have a problem with it. I mean, this is FTIR. You get noisy spectra sometimes.

Q Is noisy spectra the reason why you do multiple scans?

MR. JACKSON: Objection, form.

A Could be.

BY MR. THOMAS:

Q In any event, you'd defer to Dr. Dunn to answer this?

A I mean, you're going down this line of questioning that I'm really -- it's Dr. Dunn's work. It's

kind of hard for me to speculate on these things.

Q Okay. Now, for all three of these spectra -- actually, there are 15 spectra, three different devices, five spectra for each. The spectra themselves are truncated. They're stopped at about the 1,100 level. Do you see that?

A Yeah.

Q Why is that?

A Well, again, the peaks that we were interested in were the carbonyl and hydroxyl. And just to make it easier for the reader to read the paper, in that range of the spectrum we're not necessarily expecting changes, so they're not shown here.

Now, whether Dr. Dunn went out to those wave numbers, I don't know. But what we tried to show here, these are representative spectra to give the reader of the paper an idea of the changes that we saw. That's the purpose of this figure. So over what range he ran it, I don't know. You'd have to talk to him.

Q Okay. Have you ever seen spectra for the meshes that are depicted in Figure 2 that are complete FTIR spectra?

A A can't remember. I don't know.

Q Do you remember Dr. Thames and Dr. McLean opining in their report that had you displayed the additional data

that you would have showed that this was water confounding your FTIR spectra?

MR. JACKSON: Objection, form.

A I haven't heard that before. I don't know how they could make that opinion without seeing the spectra. I haven't seen that.

BY MR. THOMAS:

Q You haven't seen that?

A No.

Q All right. But any questions in that regard would be best directed to Dr. Dunn?

A You're just going to have to talk to Dr. Dunn because that's not -- I didn't do it. I think the question that we're going after in the papers was clear, and we explained the methods we used, and reviewers accepted it. There were no concerns about this. That's why it got published.

And those types of detailed questions about the data and how far you ran the spectra, Dr. Dunn would be the one that would have to answer that. It's not my data.

Q If you go to the Lynx mesh in Figure 2, week 4, you agree that they show no peaks either at the carbonyl or the hydroxyl peak?

A You know, again, same as before. I don't know that I'd say there's no peak, but it's much smaller.

Q And then in week 5 there's, at least for the Lynx, there's a much larger change than either the ADV or the TVT. Do you agree with that?

A Yeah, that peak is bigger.

Q Do you have any reason or opinion about why the peaks that you found in the Lynx are so much higher and bigger than the peaks that you found in either the ADV or the TVT?

A No, that really wasn't the purpose of the paper. The purpose of the paper was not to compare meshes. The purpose of the paper was to answer the question whether mesh stabilized with antioxidants can oxidize. That was the question.

We were not trying to look for differences between the meshes. That was -- that's not a question we were really addressing.

Q But does this analysis -- strike that. But the three meshes were both subjected to the same conditions?

A Yeah.

Q And the same tests?

A Yeah.

Q So is it unreasonable to compare the finding in week 5 to the TVT to the finding in week 5 to the Lynx?

A Well, you can make whatever comparison you want, but that's not a question we're going after in this study.

That wasn't -- you know, we weren't trying to make comparisons between different types of mesh.

We were just -- we know that they're all stabilized with antioxidants, so we were asking the question, can it happen? It happened in all three of them. That's what I can say.

Q Okay. Now, based on past litigation, I know that you're aware of the antioxidants that are contained in TVT.

A Yes.

Q Are you aware of the antioxidants that are contained in Boston Scientific?

A I'm aware of them. I don't remember exactly what they were and can't really -- even if I did, I can't really say what they are. I believe that I have seen those formulations.

Q Is it different than the TVT?

A I can't remember.

Q Do the different peaks that you see in weeks 5 for the TVT and the Lynx tell you anything about the differences in the mesh?

A Again, I think -- I thought I answered that. I'm not willing to -- based on these data, that's not discussed in the paper. That's not a question we were trying to answer. I'm not going to look at these spectra and conclude that there were significant differences because that's not a

question we were testing. That's outside of scope of what we did.

Q Okay.

A Anybody can look at that and draw any opinion that they want, but that's not my opinion. I don't have an opinion about that.

Q That's fine. Now, the analysis that you show in Figure 2, is it fair to describe this as an accelerated oxidation study?

MR. JACKSON: Objection, form.

A I've answered this before, too, but I don't know that I would use the term "accelerated."

I mean, essentially I think the way I've answered this before is that you -- this medium simulates that privileged pocket between the macrophage and the material surface, and so it's essentially like you're exposing the entire material to that privileged environment.

So I don't know that I'd call it accelerated. I think what this method does is, it produces hydroxyl radicals, which are reactive oxygen, and so it simulates what can happen in the body. That's what I think has been published about this medium, and I've published other papers on it. We talked about it before.

Q That was the prior paper that you presented, different organizations, correct?

A It what?
Q I haven't talked to you about the Talley paper before. I've never asked you questions about that before.
A No, but some other Ethicon attorneys have.
Q Not in the context of Talley?
A No, but it's the same answer. I've been asked about this medium before. I mean, the medium simulates the microenvironment between the macrophage and the adherent -- well, I didn't answer that very well. It simulates the environment between the macrophage and polypropylene surface.
MR. THOMAS: Let me show you Exhibit No. 4.
(Exhibit 4 was marked for identification.)
BY MR. THOMAS:
Q This is the paper that we've talked about before; correct?
A Yeah. This isn't a paper. This is a published conference proceedings.
Q Just so we're clear, you don't rely upon this test and this data in the opinions that you're giving in this case; correct?
MR. JACKSON: Objection to form.
A I don't remember if I cited it in the report, but this is a conference proceedings that was published before the paper. So the paper basically, I think, includes all of

these data. I haven't looked at it recently, but I believe, just looking at it right now, the paper includes the data in this conference proceedings.

So I don't want to say I'm not relying on it, but it's, you know, it's a paper -- most of what's in this abstract is incorporated in the paper.

MR. JACKSON: I just want to state for the record this was Exhibit 3 at his last deposition.

MR. THOMAS: I understand that. The reason why I asked is because I understood --

THE WITNESS: I'm not sure what you're getting at, I guess.

MR. THOMAS: I'm not either. I don't want to plow old ground.

THE WITNESS: I understand that. I'm not sure what you're asking.

MR. THOMAS: I didn't take the last deposition. I think Mr. Hutchinson did.

BY MR. THOMAS:

Q Let me back up because I think I may be talking about different things.

A Okay.

Q There is yet other papers about other work that you did that you presented I think in Europe, and that was the subject of a motion in the Boston Scientific litigation,

and after that time you stopped relying upon that data in your opinions in the case.

MR. JACKSON: I'm going to object to form of the last question. I think we're getting pretty far afield here. We're talking about a different litigation.

MR. THOMAS: All I'm trying to do, Tim, is to limit his opinions because -- I don't mean to make it a speech, but I'm trying to shortcut this.

BY MR. THOMAS:

Q You did some earlier work that you presented, and we went through the background data. We went through all the stuff.

A I think I know where you're going.

Q At some point you stopped relying on that data in your opinions in the case. All I want to do is establish that you haven't changed your mind and are now relying on testing and results that you reported before and presented before that you previously withdrew.

A I know this is your question on the table. It would really help me out to just deal with this head-on if I could talk with counsel for a few minutes.

Q Sure.

MR. JACKSON: Could we take a two-minute break?

THE WITNESS: I'm not trying to give you a hard time.

MR. THOMAS: I'm not worried about that because I want to make this quick and easy too. Let's go off the record.

(Recess was taken from 10:22 to 10:32.)

BY MR. THOMAS:

Q Doctor, are the FTIR spectra that are on Figure 2 of Exhibit No. 1 the result of tests that we've previously discussed in deposition, or have you done a second set of tests?

A No, we haven't done a second set of tests.

Q Okay. Just so we're clear -- and I think we talked about this before because I think I asked you questions about it -- some time ago you conducted a five-week oxidation study that you presented at least at one conference and disclosed those opinions in an expert report; correct?

A That's right.

Q After the disclosure of those expert opinions, for whatever reason you stopped relying upon the test results in that report for your opinions.

A Yes. Yeah, I didn't rely on the test data.

Q Is it fair to understand that now that the data has been published that you are now relying on that data for your opinions in this case?

A I don't -- well, I don't remember exactly what

was in those test data. I don't think we had a lot of the analysis that we presented in this paper.

Q Exactly right.

A So the raw data we looked at and did some additional analysis and thinking and submitted paper, a publication which was peer-reviewed and published. So we did not repeat the experiment, but we did more work on the analysis to basically present the paper in a form that could be published.

Q Right. To be fair, I think the XPS data is new?

A I believe it is, but I can't remember exactly what was in that report.

Q And the AMS explant analysis is new?

A I don't think that was in any test data -- I can't remember. To the best of my knowledge, I believe it's new, but I just can't remember what Dr. Dunn disclosed in his test data.

Q Okay. Dr. Guelcher, if you look back at Figure 2 on page 7, the carbonyl peaks that are there that are mislabeled with the gray arrow, do you know if those carbonyl peaks appear at the same place for each mesh?

A I'd have to go back and look at the raw data. There are multiple -- there can be multiple carbonyl peaks. I can't remember if they're different for each.

Again, that's not what -- we weren't answering

that question in this paper, so I really don't think we looked at it. We were just looking at that -- well, we explained what we did. 1,500 to 1,750 is where you'll see those carbonyl peaks, and we weren't looking for differences between products or materials.

Q You agree that an FTIR is designed to generate a fingerprint for a particular substance?

A I don't know that I'd say it that way. Basically the FTIR gives you information about bonds based on vibration frequencies. But carbonyls -- I mean, I think this has come up in previous depositions -- there can be multiple peaks. This is all even in some of the Ethicon documents that I cite in my report. There can be multiple carbonyl peaks, and we just didn't look for differences between materials.

Q Would you expect polypropylene in different meshes that are exposed to the exactly the same conditions as you did in your study in Exhibit 1 to display the same carbonyl peak if in fact it was oxidized polypropylene?

A I'm going to have to go to my report for that one. I know that it's in here.

I think the best I can answer is like I did. There are multiple species. There are a number of Ethicon documents reporting different carbonyl peaks that could be resulting from different species. I wouldn't necessarily

expect different materials from different manufacturers to have different peaks. I can't rule it out. I don't know that -- it's just, there's just multiple species, and it can be difficult to assign some of them to specific bonds, you know, real precisely.

This goes back to what I was saying about the difference between XPS and FTIR. I mean, I can say broadly that if the polypropylene is oxidizing based on reaction mechanism, I would expect to see carbonyl peaks, and that's what we tested in this paper, but we just weren't looking at that level of detail for differences between groups.

Q I want to talk now about the AMS explant that Dr. Iakovlev supplied. Do you know how he scraped it?

A Again, you'd have to talk to him about those details. I think you know Dr. Iakovlev's papers, but he prefers to work with dry mesh to get around this protein cross-linking issue that Dr. Thames referred to.

So Dr. Iakovlev has been doing it for some time. I've seen his microscope. I've seen his lab. Exactly how he does that procedure, I don't have the details.

Q It's fair to understand, from a review of Exhibit 1 or Exhibit 2, there's no way for another researcher to replicate this cleaning technique. Do you agree with that?

A I don't agree with that. I think he gave enough

detail in the paper that obviously satisfied the reviewers as to how those materials can be cleaned. He manually dissected it under a microscope with tweezers and a scalpel blade. I think that can be replicated. I don't see a problem with that.

Q With all due respect, the only place I saw for a description of his methodology is on page 1 of Exhibit 2.

A I was looking at page 5 in the paper where he says -- the X-ray photoelectron spectroscopy paragraph, he says, "Scraped fibers in which the outer layer was mechanically removed using tweezers and a scalpel blade under dissection microscope."

Q Is that the extent of methodology that you're aware of?

MR. JACKSON: Objection to form.

A Yeah. I mean, I think it sounds pretty straightforward. He's been doing it for some time. The reviewers were fine with it. I mean, it's a mechanical dissection of tissue. People do that.

Again, if you wanted all the details, if he has a protocol and all that, he would have to address that. I mean, I think for a paper, this is a reasonable description of the methodology. I'm looking on Exhibit 2 to see what's written there.

BY MR. THOMAS:

Q The first page.

A Yeah, so we don't describe -- referring back, this is just supplemental material. So I think the primary description of what he did is in the paper.

Q Okay. Can you tell how much force he used in scraping, from the paper?

A Well, I mean, I think the point of what he was trying to do was to be as gentle as possible without -- basically the purpose is -- you know, when you say the outer layers mechanically removed, that means that when you look at these under a microscope, you'll see these layers of tissue, and you can gently remove them with a pair of tweezers. That's what I understand that he did.

Q How thick is the layer of protein that's absorbed onto the mesh material?

MR. JACKSON: Objection to form.

A Absorbed, or do you mean adherent protein? I'm not sure what you mean.

BY MR. THOMAS:

Q I'll use your term, "adherent protein." How thick was that layer?

A I'm not sure.

Q On the order of a few microns?

A I don't know.

Q Do you know how thick the blade is on a scalpel that he used, how it compares to the thickness of the proteins on the mesh?

A I don't. Again, these types of detailed questions -- I don't know those types of details. Dr. Iakovlev did this, and I can't speculate on those types of things.

Q Was there any consideration to testing the scraped mesh explant for other oxygen-containing molecules such as esters or cholesterols?

A Well, I mean, again, we have to rely on what the XPS can tell us, and the XPS can tell us information about atoms that are there and the bonding. So esters are going to have carbonyl groups in them. It tells us about what molecules are there and the way that they're bound to each other.

Q So you're looking at the data on the table that's on page 4, Exhibit No. 2?

A I was referring back.

Q Is there anything about the data on page 4 of Exhibit No. 2 that tells you that the oxygen that was found on the mesh explant was not an ester or a cholesterol?

A I mean, it is an ester. I mean, I'm not sure what you mean by ester. I mean, it's an ester bond. I mean, it's -- well, it's not ester bond. It's a COO.

That carbonyl is present in an ester. If you look at the degradation products -- I have to go back to this. So I see what you're saying. I mean, an ester bond would also have that carbonyl. It could also be, I think, carboxylate. So it's not -- the XPS is just telling you about those specific types of bonds. So, like in protein, you could have esters, right. So it's -- I'm not being very clear.

The XPS tells you again about the type of bond. You could have a carbonyl and an ester bond. It's also present in the degradation of product from the polypropylene.

Q Right. And cholesterol may also appear in the carbonyl group?

A Maybe. I'd have to look at the structure.

Q Why didn't you do a controlled experiment on a pristine AMS mesh?

A What do you mean by "controlled experiment"?

Q Do the same testing XPS on a pristine AMS mesh.

A I don't remember.

Q Did you have that discussion?

A I don't remember.

Q Did you have pristine AMS mesh available to you?

A I don't remember that either. Dr. Dunn had all those materials. So I can't remember that one either.

Q What did you do to rule out contamination of the explant?

MR. JACKSON: Object to form.

A Contamination?

BY MR. THOMAS:

Q Yes. Something from the environment that didn't come from the mesh when it was implanted in the patient.

A I mean, we use standard methodology for XPS analysis, according to Dr. Rogers' papers. We removed the protein mechanically the best we could. We tested, compared the untreated to the treated -- and I'm sorry -- untreated to the scraped. That's what we can do. I mean, we have no evidence to believe there was significant contamination that would alter the results.

Q But you didn't take any steps to confirm that the AMS explant had not been contaminated?

MR. JACKSON: Objection to form.

A I'm not really sure. Again, Dr. Rogers did that work. It's difficult for me to -- I mean, we used existing methods that we've used before to clean the mesh and to analyze it. Dr. Rogers has published on XPS. I've published with her on XPS. We use standard methods and protocols for doing that work. There's no evidence to suggest there was contamination. So that's kind of the way the science is done.

BY MR. THOMAS:

Q Doctor, would you turn to page 6 of Exhibit 1. Page 6 of Exhibit 1 includes a paragraph called "Surface degradation caused by SEM."

A Yes.

Q And who conducted this work?

A Dr. Dunn.

Q Do you know what kind of scanning electron microscope was used?

A That's hard to answer. We've replaced that instrument at Vanderbilt. I can't remember where we were on that when this work was done. Maybe -- well, let me see. It might say in the -- we have several different SEMs. It's Hitachi. We have a newer one now, I think.

Q What is it about the Hitachi SEM that allows measurement of peak depth?

A Peak depth?

MR. JACKSON: Objection to form.

A Well, we used --

BY MR. THOMAS:

Q You have a number of measurements in this paragraph going from 1 micron to 10 microns. How are you able to measure that?

A Well, I mean, as you can see, these are -- we're saying greater than -- you know, these are not -- we didn't

do statistical analysis on these measurements.

So the flaking, we have a scale bar on the SEM, and you can see that those flakes and peeling features are greater than 10 microns based on that scale bar. The depth of the pits is a little bit more difficult. You could estimate that to be in the range of a micron. We were just trying to give some idea of the length scale of the features.

Q Is it fair to say the numbers there are estimates?

A I would say they're semiquantitative numbers based on the images that are shown in the paper.

Q If you go to page 9, there are scanning electron microscopy images. Are there more images than what are contained in the report?

A So, I mean, it's the same for Figure 2. These are representative images to give the reader some perspective on what we saw. We -- I think we list them in the report. I'm sorry. I keep saying -- this is a paper.

Q I understand.

A A published paper. I'm getting confused. So in this paper we are -- so I basically -- we used low, medium, high-magnification images. I think in the methods we discussed how many images we took of each one, 5 to 15 images of each specimen. It just depended, it seems, on the

specimen. So we have multiple images. These are representative ones to give some perspective on what we saw.

Q And you would expect Dr. Dunn to have those images?

A Yeah.

Q Was he the one that provided the measurements and data that went into the paragraph I've just described on page 6?

A That was probably me. I can't remember exactly. I probably did that.

Q How did you do that? By looking at the scale bars?

A Yeah. So you can look at the scale bar, and you can kind of draw a line on the feature. You can see that it's -- the purpose of like the greater than is to show that it is semiquantitative. We're giving some idea of a length scale. We didn't do specific measurements on those features. We just were trying to provide some perspective on the length scale.

Q So other than the scale within the SEM itself, there was no effort to have a more precise measurement?

MR. JACKSON: Objection to form.

A You know, it's just difficult to measure that. The depth of a pit, you know, you could do profilometry, but it's not a flat surface. It's difficult to measure that

depth precisely. So we were doing the best we could from these images.

BY MR. THOMAS:

Q And using the scale that's in there?

A Yeah.

Q Do you recognize in the paper that the flaking and pitting that you observed and report on page 9 in the SEMs is different from the transverse tracking that's been reported in other papers; correct?

MR. JACKSON: Counsel, when you say "report," we're talking about the published paper, right?

BY MR. THOMAS:

Q Dr. Guelcher, it's fair to understand that you reference in your paper the fact that the flaking and the pitting that you report and show in Figure 3 on page 9 of this paper is different from the transverse cracking that has been reported by others?

A I think we addressed that in the discussion. So there's some -- yeah, so the last paragraph of discussion, you know, the point that we're making there is, this corrosion and stress cracking can happen when you have a combination of mechanical forces and chemical degradation, and in this experiment we only had chemical degradation.

So we would not expect to see necessarily those transit cracks. It's the combination of forces, say

contractile forces from cells that infiltrate the mesh. So it's a combination of those forces and the chemical environment, chemical degradation that causes those cracks, and we believe that's why we didn't see it. That's what this discussion is saying.

Q Was there anything about this experiment that prevented you from including some application mechanical force to try to replicate the transverse cracks?

A Well, it can be done. It's just this was a first step. I mean, the first question we wanted to answer really is, can something oxidize? That was a question in this paper.

I mean, to answer the cracking question, you would have to include some kind of stretching protocol, and that takes considerably more resources, time, effort and work. And we thought it made sense to start with the oxidation question since, you know, the degradation is a consequence of the oxidation. So that's why we started with that question, and that's why we didn't do mechanical forces in this study.

Q Do you have plans to do any further study which would include the application of forces to try to replicate the transverse cracking?

A I mean, these are research studies that are funded by external sponsors, so I can't really talk about

what we're doing.

Q You can't answer the question?

A No, I can't. It's research. I mean, I can't really talk about any research that we're doing. For this Wave 5 report on the line and these documents we've been talking about -- I just can't really talk about what we're doing right now. We're not relying on it.

Q Do you have ongoing studies into the oxidation of polypropylene?

A I just can't talk about it.

Q Can you answer yes or no?

A No, I can't answer yes or no. I can't really talk about what we're doing. It's an externally funded research project. It's confidential.

Q Can you tell me who's funding the research project?

A I mean, I never said there was a research project. I'm saying that, you know, our plans and ideas, these are all -- it's research. It's confidential.

Q Okay. We may have to come back to that. How do you measure embrittlement?

MR. JACKSON: Objection, form.

A I think it's in my report, but I'll -- embrittlement you could -- you could measure by mechanical testing, dynamic mechanical testing. It's a mechanical-type

test.

BY MR. THOMAS:

Q Have you done any embrittlement testing of any of the meshes that you've tested in Exhibit No. 1?

A We have not. Again, it's a very technically challenging test to do, so we decided to start with things we could do using known and established methods.

Embrittlement requires a certain kind of -- it would be more difficult to do, and we have to -- we haven't done it.

MR. THOMAS: Let me take a break. Give me a few minutes. I may be close to wrapping up.

MR. JACKSON: All right.

(Recess was taken from 11:00 to 11:05.)

(Exhibit 5 was marked for identification.)

BY MR. THOMAS:

Q I'm going to hand you now what's been marked as Deposition Exhibit Number 5, the Second Amended Notice of Deposition. This requested that you bring with you to the deposition a number of things. I've received the filing by your counsel about objections. I've also received some billing information, a copy of the 2017 published article, which is Exhibit 1, supplemental data which is Exhibit Number 2.

There is a deposition request that you also

produce all of the underlying data for the Exhibit Number 1 and Exhibit No. 2, and I believe we've covered that today in your deposition, that is, to the extent that that data is available, it's in the custody or control of the people who conducted the work and not in your current possession. Is that fair?

A That's right.

Q And you did not ask them to give that information to you for purposes of this deposition; correct?

A I did not because that's just not how things are done. I think if you want somebody's data, you have to ask them directly.

Q Have you had any -- as corresponding author, have you had any inquiries about the work that went into the Talley study?

A I've had requests for the paper, and I've sent that to people, but I haven't had any detailed questions about it.

Q Other than producing the paper, have you discussed with anybody else your methodology or the results that you've reached?

A Not that I can remember.

Q Where does Ms. Talley live now, Dr. Talley?

A She lives in Maryland. She works for FDA.

Q When did she take her job with FDA?

A Maybe a year ago. No, six months. Within a year.

Q What does she do for FDA?

A She is a reviewer of medical device applications.

Q Where does she work in Maryland?

A She works at FDA.

Q I understand that, but Maryland is a big state. I don't mean to be flip, but I'm just trying to find out which city.

A I don't know. I don't know where exactly she lives.

Q Is it closer to Washington D.C. or closer to Baltimore? Do you have any idea?

A Probably D.C.

Q And Dr. Rogers still work at Vanderbilt?

A Yes.

Q Dr. Dunn still at Vanderbilt?

A Yes.

Q Were you the person who was responsible for organizing the study?

MR. JACKSON: Objection, form.

A I would say that Dr. Dunn and I did that together. We thought about what question we want to ask, how we could design the study, then we maybe talked to Dr. Iakovlev about explants.

So probably mostly it was probably Dr. Dunn and me planning the study.

BY MR. THOMAS:

Q On page 13 of Exhibit No. 1 under the disclosure statement and funding it says, "Russell F. Dunn is the owner of Polymer Chemical Technologies, which sponsored the work."

A Yes.

Q Are there other employees of Polymer Chemical Technologies, to your knowledge?

A I don't know at the moment. You would have to ask Dr. Dunn about that. I don't know if he has any employees right now.

Q There's been a time when that was just him?

A I mean, his business has changed over the years. Sometimes he's had employees, sometimes not. So I don't know right now. When this work was done, I don't know.

Q The work was supported by Polymer and Chemical Technologies, LLC, Grant Number VU1349. Did you prepare a grant request to Polymer and Chemical Technologies for this work?

A No.

Q What is -- is VU Vanderbilt University?

A Yes.

Q So how does Vanderbilt University 1349 obtain a grant from Polymer and Chemical Technologies?

A I mean, any company can enter into an agreement called a sponsored research agreement. I've done this before with other companies. Any company can enter into an agreement with the University to sponsor research. It's a standard thing.

Q Is it your suggestion that Vanderbilt is a sponsor of this research?

A No.

Q Okay.

A It's a sponsored research agreement so an external sponsor -- could be a foundation, could be federal government, could be a company -- enters into a contractual relationship with Vanderbilt University where they agree to sponsor research at Vanderbilt. So they pay for the research, but the research is done at Vanderbilt. So there's a contract that regulates that.

Q So there's a contract for this study between Polymer Chemical Technologies and Vanderbilt University?

A I don't know if it's for the study. Again, you'd have to ask Russell about the details of how his company -- his relationship between his company and Vanderbilt is something I can't really address.

What I can tell you is that when this says Grant Number VU1349, that means that there's some sponsored research agreement between Polymer Chemical Technologies and

Vanderbilt. The scope of that agreement, I don't know the details. That's all I can say from that sentence.

Q How much was the grant?

A I don't know.

Q Was there any other financial support to the work in Exhibits Number 1 and 2 beyond what was supplied by Polymer and Chemical Technologies, LLC?

A No.

Q Do you know whether Polymer and Chemical Technologies, LLC obtained money from any other source to fund this research?

A I don't -- again, I don't know the details of how the company contracted with Vanderbilt. I don't know those details. I can just -- from the way that's written, I can infer that there's a contract.

Q If you had any conversations with any lawyers about obtaining money to be supplied to Polymer and Chemical Technologies, LLC that would be used as a grant to fund the work in Exhibits Number 1 and 2?

MR. JACKSON: This is clearly privileged information you're asking him about.

MR. THOMAS: Oh, I don't think so.

MR. JACKSON: No?

A Again, I have no relationship with Polymer Chemical Technologies. This is Russell Dunn's company.

He's the owner, as it says here. I don't -- I don't know -- I mean, I can't answer these questions. You're asking questions about how Polymer Chemical Technologies, who I have no relationship with, is doing business. I can't answer that.

BY MR. THOMAS:

Q I asked you whether you've been party to any conversations where it was determined that lawyers in this litigation would fund Polymer Chemical Technologies, LLC to supply the grant for the work that's done in Exhibits 1 and 2.

MR. JACKSON: I think to the extent you're asking about conversations between attorneys and the witness, that's privileged information.

MR. THOMAS: Are you directing him not to answer?

MR. JACKSON: I think he's already answered the question.

MR. THOMAS: Are you directing him not to answer?

MR. JACKSON: No, I'm not, because I think he's already answered the question.

BY MR. THOMAS:

Q The question is, have you been party to any conversations with lawyers where it's been discussed lawyers funding Polymer Chemical Technologies, LLC grant for the work that's done in Exhibits Number 1 and 2?

A I mean, I can't really discuss all the conversations we have with counsel. I mean, I --

Q He hasn't instructed you not to answer. He's permitted you to answer the question.

MR. JACKSON: I'm instructing him not to answer to the extent it calls for any communications between himself and attorneys.

MR. THOMAS: That's fine. We'll fight that one.

A Let me think about this for a second, all right. I'm trying not to --

MR. JACKSON: I think he's already given you an answer to the question.

MR. THOMAS: I'm not going to argue with you.

A Let's just -- can we just go with what's written here? Can we do that?

BY MR. THOMAS:

Q I can read it as well as you can. I'm just trying to figure out what else is involved that's not here.

A Well, what did we disclose? Russell and I -- Dr. Dunn and I have disclosed these matters to the University, and we have -- we have an annual disclosure, and all of this has been disclosed.

In the paper we disclose several things. We say that Russell Dunn is the owner of Polymer Chemical Technologies. Polymer Chemical Technologies sponsored the

work.

I mean, that means that that company, through this grant, VU1349, gave money to Vanderbilt, and this work was done within that context.

I don't know the details of that contract. I don't know if it funded other work. All I know is, there's a contract between PCT and the University, and this work was done within the context of that contract. Dr. Iakovlev and I disclosed the fact that we provided opinions in these cases. So this is what we disclosed.

To go into like conversations with attorneys about paying for experiments, I can't talk about that. That's -- this is, you know, privileged information with attorneys.

Q Okay.

A We did not say that they funded the study. This study was funded by the company. But I can't go any further than that. I can't --

MR. THOMAS: I keep forgetting I've got more time than I thought I did. I'm on eastern time. Doctor, I'm going to quit. Thank you very much for your time.

THE WITNESS: Thank you.

MR. THOMAS: Have a safe trip to Australia.

MR. JACKSON: I have no questions.

(Deposition concluded at 11:17.)

CERTIFICATE

I, Gina Hawkins, Licensed Court Reporter for the State of Tennessee, do certify that the above deposition was reported by me and that the foregoing transcript is a true and accurate record to the best of my knowledge, skills, and ability.

I further certify that I am not an employee of counsel or any of the parties, nor a relative or employee of any attorney or counsel connected with the action, nor financially interested in the action.

I further certify that I am duly licensed by the Tennessee Board of Court Reporting as a Licensed Court Reporter as evidenced by the LCR number following my name below.

Subscribed and sworn to before me when taken this 17th day of August, 2017.

_____

GINA HAWKINS, LCR #780

Expiration Date: 6/30/2019

ACKNOWLEDGMENT OF DEPONENT

I, SCOTT GUELCHER, Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

SCOTT GUELCHER, Ph.D. Date

Subscribed and sworn to before me this

___ day of _____, 20__.

My commission expires:_____

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Notary Public

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ERRATA

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LAWYER'S NOTES

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